DEVELOPMENT, VALIDATION AND RELIABILITY TESTING OF A SENSORY OUTCOME MEASURE FOR HYPOXIA INDUCED CEREBRAL PALSY CHILDREN

Synopsis Submitted To

Maharishi Markandeshwar (Deemed to be University)

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1. Introduction

Hypoxic ischemic encephalopathy (HIE) is a main cause of cerebral palsy (CP). In this condition blood supply of brain is obstructed causing hypoxic-ischemia. According to the studies up to 60% of infants with HIE will die by the age of 2 years, and survivals have so many disabilities like mental retardation, seizures, and CP.[1] It this condition, group of disorders cause permanent disturbance of the movement and posture development, limitation in activities. These disorders are non-progressive occurring in the growing fetal or infant brain. With the motor disorder some other sensory impairments like awareness, memory, communication ,performance, epilepsy, and secondary musculoskeletal problems are seen.[2] According to the studies prevalence of CP is around 2 to 9 per 1,000 live births .[3] It is a common disorder of child. It is a non progressive chronic condition which is static in nature .These children have faced so many problem such as epilepsy, difficulties in feeding, visual problems and hearing impairment.[4] Other like abnormal change in muscle tone and limitation in activity.[3]

The pathologic changes occurs in HIE are because of the impaired cerebral blood flow and oxygen to the brain.[5]

The causes of HIE are intrauterine factor such as restriction in fetal growth , placental vascular disorders, Some peripartum as placental abruption and some events at the neonatal period as intraventricular hemorrhage, and neonatal stroke.[3] Ischemia causes more release of pro inflammatory cytokines, oxidative stress, maternal growth factor deficiency, extracellular matrix modifications, and increased release of glutamate, triggering the excitotoxic cascade.[6]

So many other neurodegenerative conditions, including various metabolic and genetic disease may exhibit analogous signs and symptoms like CP.[7]

Children with CP may show some other symptoms as abnormal movements like athetosis, chorea, and dystonia. Some are mixed CP those who shows a combination of features such as epilepsy, feeding, nutrition, growth problem, mental retardation, bladder dysfunctions, bowel dysfunction, drooling, sleep disturbances, hearing loss, visual abnormalities, orthopedic associated sensory impairment.[8] The motor disorders of CP are associated with some other disorders like impaired memory, communication, sensory awareness, behavioral abnormalities,

convulsion disorders, or a combination of these features.[9]

Classification of CP are based on the basis of Pathophysiology of brain as if the cortical involvement occur choreoathetosis exhibits, if cerebellar involvement occurs it resulting in abnormal movements, if involvement of basal ganglial occurs balance disturbance exhibits.[4] CP is also classified according to the types of motor impairment like Paresis, Hypertonia, Hypotonia, Dystonia, Dyskinesia and ataxia. It is also classified according to the body structure affected like all four sides, both the lower limb and any one side of the body. The sign and symptoms of CP are also based on the pyramidal and extrapyramidal involvement for example Pyramidal lesions causes spasticity, hypertonia, increased deep-tendon reflexes and extensor plantar response and Extrapyramidal lesions shows rapid or slow involuntary movement of fingers or toes and impairment of voluntary movement (and other forms of abnormal regulation of tone), abnormal position control, and incoordination.[9]

CP is diagnosed on the bases of laboratory investigations along with some sign and symptoms like delay in developmental , toe walking , persistent fisting, Early indicators are microcephaly, epilepsy, irritability, poor sucking, handedness before 2 years of age as well as scissoring of the lower limb and retained primitive reflexes will also an indicator for CP. Brain CT and Brain MRI are more sensitive tool for investigation.[4]

Assessment of CP child should done by clinical information as well as a detailed history from medical record, interview of caregiver ,sensory examinations and motor assessment should carry out. Sensory assessment include measures of fine touch and proprioception.[10] Management of CP include drug treatment as for spasticity antispasmodics, anti cholinergic drugs for managing uncontrollable body movements and anticonvulsants for the treatment of seizures. Orthopedic and neural surgeries are also used for joints, muscles, tendons and nerves. Casts, splints & braces are also used.[11] Sensory processing is termed as the sensory information by neural system of the body; it is the functions of sensory organs as well as peripheral & central nervous system. Sensory information from the surroundings and from the body parts transmit to the brain and then brain arrange, combine and coordinate this information for appropriate responses. Sensory impairments also affect the motor functioning of an individual. [12]

1.1 Need of the study

The present scales are not able to give complete assessment for sensory issues in HIE children for Indian population. Therefore, there is a need for the development of scale to completely measure the above domain in HIE children.

1.2 Purpose of the study:

The main rationale is to build up a sensory outcome measure for assessment of sensory issues in HIE children using a systematic approach.

1.3 Aim: To study the sensory outcome measure for development, validation and reliability testing of hypoxia induced cerebral palsy children.

1.4 Objectives: The study is based on following objectives:

1.4.1. To develop an outcome measure of sensory testing in children with Hypoxia induced cerebral palsy children.

1.4.2. To validate the Sensory outcome measure for Hypoxia induced cerebral palsy children.

1.4.3. To evaluate reliability of Sensory outcome measure for Hypoxia induced cerebral palsy children

2. Review of literature

2.1 Amira Eid mohamed et al **(2019)** worked on cortical sensation and fine motor skills and stated that there is a relation between cortical sensations and fine motor skills in spastic CP. So , cortical sensations should also be examine in children with fine motor skill problems.[13]

2.2 Sara Jorquera et al **(2017)** worked on systemic review for evaluation of sensory processing distinctiveness in children and they found that only 15 tests are available that have validity and reliability, mainly for the United State population. Out of them only nine tests are applied to children in playgroup and for 12^{th} class. [14]

2.3 Max J Kurz et al **(2017)** worked on Hyper gate somato sensory stimulation of the foot and stated that somato sensory cortical oscillations are weaker in the children with CP.[15]

2.4 Serkan pekcetin et al **(2016)** stated that preterm infants must be examine for the sensory issues and sensory interventions should be given to them for improvement.[16]

2.5 Catharine Critz et al **(2015)** examine the sensory processing issues in children and find that it is important to examine the sensory processing challenges in children because the sensory issues may affect the behavior and learning of child.[17]

2.6 Alisha Ohl et al **(2012)** stated that the sensory profile have test–retest reliability and internal consistency and supports the use of quadrant scores for analyzing children's sensory processing patterns.[18]

2.7 Megan Louise et al **(2012)** stated that Most of the children with UCP exhibit poor tactile perception and they study them by using tactile registration, single-point localization, double simultaneous, static and moving two-point discrimination, haptic perception, and texture perception.[19]

2.8 Ted Brown et al **(2010)** stated that a significant correlation is present between sensory profile and sensory processing measure and have convergent validity of the moderate level for the sensory assessment for the school aged children of Newzeland.[20]

2.9 Jason R Wingert et al **(2008)** stated that CP child shows tactile sensory deficit in both hands. Mild deficit in dominant hand and non dominant shows greater sensory impairment.[21]

2.10 A. Jerome et al **(2007)** conduct a first round study of the sensory processing abilities of children with CP and typical children and found that sensory profile is helpful for the evaluation of sensory processing abilities in CP and typical children. [22]

2.11 Heather Miller et al in the year 2007stated that sensory processing measure is reliable and valid tool, it can differentiate child with and without sensory processing issues.[23]

2.12 Dimitrios et al **(2004)** stated that motor assessment along with the examination of primitive reflexes and postural reactions are essential for early screening and a combined examination is useful for CP child.[24]

3. Methodology

The Scale will develop in following steps:

a. Definition of scale

b. All domains of sensory Impairment in CP patient's will be identify on the bases of a literature review and then consult with the focus groups that is review by experts.

c. After that an item pool will be generated.

e. Then each item will be tested for clarity and relevance (Designing the scale).

f Full administration of items and item analysis. .

3.1 Study design: A Cross-sectional study design for scale development will be used

3.2 Study Location: OPD of Subharti college of Physiotherapy (SVSU), Meerut, UP.

3.3 Study Setting: Rehabilitation Lab of SCPT OPD

3.4 Study Participants: Children suffering from HIE

3.5 Sampling method: Purposive

3.6 Subject Selection Criteria:

3.6.1 Inclusion criteria

3.6.1.1 Children suffering from HIE.

3.6.1.2 Age range from 3 -14 years.

3.6.1.3 Both male and female will be included.

3.6.2 Exclusion criteria

3.6.2.1 Children having some associated conditions (congenital malformations, cardiac pathology)

3.6.2.2 Visually impaired.

3.6.2.3 Etiological factor other than HIE.

3.6.2.4 Hearing impairment

3.6.2.5 Mental retardation

3.7 Materials to be used for data collection: CP Chair ,Colorful toys

3.8 Ethical Statement: The protocol will be submitted for approval from the Institutional Ethics Committee of Maharishi Markandeshwar Deemed to be University and from the Swami Vivekanand Subharti University.

3.9. Procedure

This is a cross-sectional study to the validation of scale and for testing its reliability. The study will follow four steps like item generation and validation, reliability testing and estimating MDC.

3.9.1. Four Steps of Construct Development

STEP 1: Definition of construct

STEP2: Generation of items and Validate them

- **Extensive review of literature and focus group**
- **Items have to be Grouped**
- **Validate the content (by experts panel)**
- **Rough draft have to be formed**
- **Pilot study done**
- **Revision of the Draft**
- **Final format should Form**

STEP 3: Testing of Reliability

INTERNAL CONSISTENSY	TEST RE TEST	INTRARATER	INTERRATER
BY CRONBACH,S ALPHA	• SESSION 1 (By principal investigator) • 7 DAY BREAK INTERVAL • SESSION 2 (Again by principal investigator)	• SESSION 1(By principal investigator) • BREAK OF SHORT PERIOD • SESSION 2(Again by principal investigator)	• SESSION 1 RATER 1 RATER 2 • 7 DAYS BREAK INTERVAL • SESSION 2 RATER 1 RATER 2 • MEAN VALUE

STEP 4: MDC

- **SEM**
- **MDC**

3.9.1.1 Step 1: Construct definition: Defining the construct what is about it.

3.9.1.2 Step 2: Item generation: This step consists of seven sub-steps. These are item generating, grouping items (designing the scale), content validation, rough draft, pilot study, revision and final format. This step will provide all items related to sensory issues in HIE patients using literature search and direct parent interviews.

3.9.1.2.1 Literature search

Literature of English language will be searched in Pub Med, Cochrane Library and goggle scholar databases in the time frame between January 1990 and February 2019. The key words which are to be used hypoxic ischemic encephalopathy, sensory scale, proprioception, kinesthesia, vibration, two point discrimination, sensory assessment scale.

For direct interview, we have to approach twenty parents of HIE children at home or OPD by the investigator and then data have to collect. These parents will be asked to generate the items that are relevant to assess the sensory impairments. First, the parents will mention different items related to sensory problems which they feel in their children. Then we have to motivate the

parents to fill as much as number of items which they feel in their daily life based on their experience. Second, asked to add more items which are not mentioned yet. By using this we have maximum number of items, which the parents felt that need to be in the scale. Then the items have to be pooled together and remove the duplicacy.

3.9.1.2.2 Grouping item

The items have to be grouped under the related domains.

3.9.1.2.3 Content validation

Then validate for its content by the panel of experts (sample of 10). The items have to be include if eight or more experts give positive response.

3.9.1.2.4 Rough draft

The items have to be accepted on the bases of suggestion given by the experts. The scoring criteria for the scale have to be formed to represent the sensory impairment on a 4-point scale ranging from 0 to 3, where 0 is no impairment and 3 is severe impairment. Middle scores represent 1 (Mild impairment), 2 (Moderate impairment). The scoring options will be designed according to the items under each domain. The total score of the scale will be 100% which means extremely severe impairment of sensory issues in HIE children.

3.9.1.2.5 Pilot study

Then Pilot study will be done.

3.9.1.2.6 Revision

Eliminate the item, which have frequency of response is less than 30% for the item.

3.9.1.2.7 Final draft

The final draft of the scale will be formed. The suitable name will be fixed for the scale.

3.9.1.3 Phase 2: Reliability testing

3.9.1.3.1 Check for internal consistency

The sample size calculated from the pilot study. Then the scale will be administered on the HIEC

by investigator. Scores will be used to analyze the internal consistency of items using Cronbach's alpha.

3.9.1.3.2 Test-retest reliability

Assessment will be done in two periods with minimum duration of seven days and not more than fourteen days by the principal tester.

3.9.1.3.3 Intrarater reliability

Estimated by administrating the scale in HIE Children on two periods with short intervals by the principal investigator when carryover or practice effects may not be an issue.[25, 26]

3.9.1.3.4 Interrater reliability

Interrater reliability **w**ill be estimated by two investigators in first session and again after an interval with these two raters.

3.9.1.4 Estimating SEM and MDC at 95% Confidence Interval (CI)

SEM and MDC will be calculated by using the formula. Significant level will be set at $p \leq 0.05$.

3.10 Data analysis

SPSS software IBM Statics 20 version will be used for statistical analysis.

3.10.1 Validity: Delphi method of validation

3.10.2 Reliability testing

Internal consistency will be estimated using Cronbach's alpha (α). Cronbach's alpha ≥ 0.8 will be considered as evidence of acceptable internal consistency. Test retest reliability will be evaluated using Intra class Correlation Coefficient (ICC). ICC will be computed for evaluating the test retest reliability for each domain scores and the total scores. For the purpose of this study, ICC ≥ 0.75 will be considered as evidence of acceptable test–retest reliability. The level of significance will be set at $p \leq 0.05$ for all the statistical analysis. Bland- Altman graph will be used to determine the level of agreement the between sessions.[27]

3.10.3. SEM and MDC at 95% CI

SEM and MDC will be calculated using the formulae. Test-retest reliability score will be used in place of reliability. Significant level will be set at $p \leq 0.05$ to minimize.

4. Conclusion

The scale, that is formed will be the appropriate outcome measure for documenting patient's impairment related to sensory issues in HIE children in India.

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6.0 Appendix

6.1 Information Sheet

Name of the Project: Development, validation and reliability testing of a Sensory outcome measure for the hypoxia induced cerebral palsy children.

Investigator: Shikha Singh

Guide: Dr. Vandana Esht

Place of Work: OPD of Subharti College of Physiotherapy and Bosco Health Care Centre

Type of Study: A Cross-sectional study

Selection of Participants: Children suffering from HIE (Hypoxic Ischemic Encephalopathy)

Voluntary Participation: The decision of participation in the study is entirely permitted by the legal guardian of the child.

Procedure: Sensory assessment have to be done with the help of questionnaire for parent and assessment done by the investigator.

Relative Risk: Child may feel fatigue

6.2 Informed Consent Form

Certificate of Consent

We read the following information, and I understand that this research will not cause any risk to my child. I have the opportunity to ask any questions about it. I consent voluntary for my child to participate as a participant in this study.

Name of Participant:……

Name of Parent of Guardian:…….

Signature of Parent or Guardian:……..

Date:……..

Day/month/year

If illiterate

Illiterate witness must sign (if possible, this person should be selected by the participant, and the individual has the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness:…… **AND Thumb print of parent**

Signature of witness:…….

Date : ……..

Day/month/year

Statement by the Investigator

I have accurately read out the information sheet to the parent of the potential participant, and to the best of my ability made sure that the person understands that the research work is not

having any risk, and health and confidentiality of participant will be maintained throughout the study.

I confirm that the parent or guardian has given an opportunity to ask questions about the study, and all the questions asked by the parent or guardian will be answered. I confirm that the individual has not been forced into giving consent, and that the consent has been given freely and voluntarily.

A copy of this form has been provided to the guardian and participant.

Name of Investigator taking the consent:…….

Signature of Investigator taking the consent:……..

Date: ……..

Day/month/year

सहमति का प्रमाण पत्र

मैंने सभी जानकारी पढ़ ली है, और मै समझता हू कि इस अध्ययन से मेरे बच्चे को कोई खतरा नहीं होगा | इस अध्ययन के बारे में कोई भी प्रश्न पूछने का अवसर है | मै इस अध्ययन में प्रतिभागी के रूप में भाग लेने के लिए अपने बच्चे के लिए स्वैक्षिक हू |

प्रतिभागी का नाम:.....

माता-पिता या अभिभावक का नाम:.....

माता-पिता या अभिभावक के हस्ताक्षर:.....

तारीख:.....

दिन/ महीने/ साल

हस्ताक्षर निरक्षर

एक साक्षर साक्षी को हस्ताक्षर करना चाहिए (यदि संभव हो तो, इस व्यक्ति को प्रतिभागी द्वारा चयनित किया जाना चाहिए और उसे अनुसंधान टीम से कोई संवंध नहीं होना चाहिए)| जो अनपढ़ है, उनके अंगूठे का प्रिंट भी शामिल होना चाहिए|

मैंने संभावित भागीदार के माता- पिता को सहमति फॉर्म का सटीक अध्ययन कराया है, और पुष्टि करता हू कि इस व्यक्ति को सवाल पूछने का अवसर मिलता है | मै पुष्टि करता हू कि व्यक्ति ने स्वतंत्र रूप से सहमति दी है |

गवाह का नाम .....

गवाह के हस्ताक्षर:.....

तारीख:.....

और माता -पिता के अंगूठे का प्रिंट

दिन/ महीने/ साल

जांचकर्ता द्वारा बक्तव्य

मैने संभावित प्रतिभागी के माता-पिता को सूचना पत्रक को सही तरीके से पढ़ाया है, और अपनी योग्यता क्षमता को सुनिचित करने के लिए कि वह व्यक्ति समझता है कि शोध कार्य में कोई जोखिम नहीं है, और प्रतिभागी के स्वस्थ्य को पूरी तरह से गोपनीय रखा जायेगा|

मै पुष्टि करता हू कि माता-पिता या संरक्षक ने अध्ययन के बारे में सवाल पूछने का अवसर दिया है, और माता-पिता या अभिभावक द्वारा पूछे गए सभी सवालो का जवाब दिया जायेगा | मै पुष्टि करता हू कि व्यक्ति को सहमति देने के लिए मजबूर नहीं किया गया है और यह सहमति मुक्त रूप से और स्वेच्छा से दी गयी है |

इस फॉर्म कि एक कॉपी प्रति संरक्षक और प्रतिभागी को प्रदान कि गयी है

प्रिंट करने वाले अन्वेषक का नाम:.....

सहमति लेने वाले अन्वेषक के हस्ताक्षर.....

तारीख:.....

दिन/ महीने /साल

6.3 Assessment form

Demographic Data

Name	
Age	
Sex	
Father's Occupation	
Address	
Contact No.	
Height	
Weight	
BMI	
Date of Assessment	

Present Chief Complaint _____

History:

History of Present Illness:

History of Past Illness:

History of Past Medical Illness:

1. Previous treatment for the same condition **Yes** **No**
2. Presently under any medication **Yes** **No**
3. Any other medical problems and treatment for the same **Yes** **No**